



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; National Children's Study (NCS)

Vanguard Data and Sample Archive and Access System (Eunice Kennedy Shriver

National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health Eunice Kennedy Shriver National Institute of Child Health and Human Development will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data

collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jack Moye, Jr., MD, Bldg. 6710B Rm. 2130 MSC 7002, 9000 Rockville Pike, Bethesda, MD, 20892-7002, or call non-toll-free number (301) 594-8624 or E-mail your request, including your address to: NCSArchive@s-3.net. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: National Children's Study (NCS) Vanguard Data and Sample Archive and Access System, 0925-0730 exp., date 2/28/2019– EXTENSION Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: NICHD requires institutional and investigator

contact information from users of the NCS Data and Sample Archive and Access System (NCS Archive). This information collected from potential data users is necessary to fulfill the requirements of their proposed research projects, ensure compliance with Department of Health and Human Services regulations for the protection of human subjects in research (45 CFR 46) and the Common Rule (45 CFR 46 Subpart A), and to document, track, and monitor the use of the NCS Archive, which provides opportunities for qualified researchers to use data and samples collected by the NCS Vanguard phase, for approved research projects. The information in addition will help NIH better understand the use of archived data and samples by the research community. There is no plan to publish the data collected under this request other than to post on the NCS Archive website the titles of approved research projects together with project investigators' institutional affiliations. The data otherwise are for internal monitoring purposes only, to assess the archive resource requirements and for quality improvement.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 109.

Estimated Annualized Burden Hours

Type of Respondent	Form	Number of Respondents	Frequency of Response	Average Time Per Response (hours)	Total Annual Burden Hours
Research scientists	NCS Vanguard Data User Agreement	300	1	10/60	50
Research scientists	NCS Vanguard Data Request Form	50	1	20/60	17
Research scientists	NCS Vanguard Data and Sample Request Form	50	1	30/60	25
Research scientists	Research Materials Distribution Agreement	100	1	10/60	17
	Total	500	500		109

Dated: November 1, 2018.

Jennifer M. Guimond,

Project Clearance Liaison,

Eunice Kennedy Shriver National Institute of Child Health and Human Development,

National Institutes of Health.

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